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I, LEANNE MYNOTT, MANAGER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2004900176 for a patent by ORAL BIOSCIENCE PTY. LIMITED as filed on 15 January 2004.

WITNESS my hand this
Thirteenth day of January 2005

LEANNE MYNOTT
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Regulation 3.2

AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION

APPLICANT: Oral BioScience Pty. Limited
NUMBER:
FILING DATE:

Invention Title: ORAL ANAESTHETIC GEL

The invention is described in the following statement:-

ORAL ANAESTHETIC GEL

Area of the Invention

This invention relates to the area of topical anaesthesia or desensitisation. In particular it relates to a topical anaesthetic which is adapted to be used on mucous membranes and can be usefully applied in the field of dentistry despite having other applications.

Background to the Invention

Local anaesthetics have been used in creams and ointments for many years. Usually however there is a problem with the penetration of the drug or chemical due to the physio-chemical properties of both the drug and the base in which it is used.

In addition one of the products used topically on non mucous membranes is a cream and is not suitable for use on mucous membranes such as in the mouth. Another product which can be used orally is a paste that has been formulated for the mouth but unfortunately does not adhere to the gum or mouth particularly well when used for dental purposes.

It has been suggested that a gel base could be used to adhere in the mouth however to date none exist which are able to provide the anaesthetic effect

required and additionally are quite unpalatable and therefore unsuitable for oral anaesthetic use.

Outline of the Invention

It is an object of this invention to provide a topical anaesthetic for use on mucosal surfaces which does not exhibit the problems outlined above. It is a further object of the invention to provide such a topical anaesthetic which is sufficiently palatable that it can readily be used for dental purposes.

The invention is a topical anaesthetic which is a gel formulation which penetrates through mucosa and is therefore suitable for dental purposes, the formulation is a gel base having an active anaesthetising agent and a flavouring agent.

It is preferred that the gel base used be Pluronic Lecithin Organogel (PLO) and that its viscosity be adjusted as required by the addition of suitable thickeners. It is further preferred that that PLO strengths range from 2% to 20%.

It is further preferred that the active agent or ingredient , otherwise referred to as the active pharmaceutical ingredient (API) be lignocaine base USP or alternatively the HCL salt. It is also preferred that other active ingredients may be tetracaine benzocaine, amethocaine or prilocaine.

In order that the invention may be more readily understood we shall describe by way of non limiting example a particular embodiment of the invention.

Example of an Embodiment of the Invention

A preferred application of the invention in the area of dentistry will be described here although the formulation of the invention could also be used for domestic uses.

This embodiment of the invention is a gel formulation that is very quickly absorbed into the mucosa. As absorption is rapid the dentist can inject anaesthetic into a patient's gum with a major reduction in pain in the injection site in as little as 30 seconds or up to 2 minutes.

Trauma is further reduced psychologically by the presence of palatable flavouring in the gel which masks the customary bitter taste of the analgesic material used as the anaesthetic.

An example of the invention to be described here is a PLO gel formulation having Lignocaine 10% and being flavoured.

Typical ingredients are as follows: Lignocaine USP 10g, Sodium Metabisulphate 0.1g, Ethoxy Diglycol Reagent 10ml, Lecithin Isopropyl Palmitate/Myristate Solution 22ml , Flavouring 12ml, Saccharin Sodium 0.2g, Stevia Powder Extract 1g, Pluronic Gel 20% up to 100ml.

The procedure for making the formulation is as follows:

- place a volume calibrated beaker on an electronic balance

- weigh Lignocaine powder into the beaker and add the Sodium Metabisulphate
- measure the Ethoxy Diglycol Reagent and Lecithin Isopropyl Mystrate (or alternatively Isopropyl Palmate) Solution and add to the beaker with a magnetic stirring bar
- place beaker on a stirring plate and stir until the ingredients are dissolved.
- add flavouring
- remove stirring bar and add Pluronic gel 20% to volume
- pour mixture into an appropriately sized unguator jar, remove excess air and mix for a few minutes.

If desired the gel may be stored in a syringe with any excess air removed or otherwise stored as desired. The air removal is preferably achieved by turning the syringe upside down and allowing the gel to settle on the plunger before removing the air.

The compounding procedure is an important part of the process as force used in mixing can encourage micelle formation. It is therefore preferred that this be reduced by using syringe to syringe techniques, a Dremel tool with mixing blade, electric mortars and ointment mills which can aid in the process.

While a variety of flavours may be used they may include the following:

PINA COLADA per 5ml

Bitterness Suppressant 5d, Pineapple 4d, Pina Colada 5d, Peach Oil 1d, Coconut 2d

YELLOW CARAMEL per 5 ml

Bitterness Suppressant 5d, Cinnamon Oil 1d, Caramel 5d

STRAWBERRY per 5 ml

Bitterness suppressant 4d, Strawberry 4d, Blackberry Oil 1d, watermelon 2d, Krisgel to thicken

ORANGE per 5ml

Bitterness suppressant 5d, orange 10d, Tangerine oil 1d

The above is an example of the gel formulation of the invention and it is envisaged that actual concentrations of ingredients can vary as can the actual ingredients which are chosen depending on the specific application.

For example the strength of the analgesic used in the gel for dentistry could be typically up to 10% lignocaine while for over the counter type medications 1% or 2% could be used.

In addition the previously suggested anaesthetic agents can generally be used up to 10% to achieve a specified effect while benzocaine can be up to 20%.

As has also been suggested the viscosity of any batch of the gel formulation can be adjusted by adding an appropriate thickener.

Clearly the concept of the invention of providing a gel based anaesthetic which is also palatable and can be used on mucosal surfaces can be achieved in a variety of ways and while a particular embodiment of the invention has been described herein it is to be understood that variations and modifications in the features described can still lie within the scope of the invention.

DATED THIS 15TH DAY OF JANUARY 2004

ORAL BIOSCIENCE PTY. LIMITED
By its Patent Attorneys
A TATLOCK & ASSOCIATES